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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,017	05/01/2001	Ta-Shuong Yeh	6230	5639

7590 10/01/2002
Samuels, Gauthier & Stevens LLP
Suite 3300
225 Franklin Street
Boston, MA 02110

EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant(s)	Applicant(s)	
	09/847,017	YEH ET AL.	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of information disclosure statement filed 8-2-01 and preliminary amendments filed 9-24-01 and 1-9-02 is acknowledged. Requested amendments to the specification have been made and new claims 25-33 have been added.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

3. "Type" in claim 13 is indefinite since the scope of the expression is extended so as to render the microcrystalline cellulose indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claims 1-10, 12-17, 22, 25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774).**

8. '774 teaches a direct tableting auxiliary and method for its making comprising particles of microcrystalline cellulose and a binder such as polyvinylpyrrolidone (PVP) where the auxiliary is produced by heating ingredients that have an initial moisture content that is sufficient to moisten the ingredients but is insufficient to dissolve the binder completely in a fluidized bed (closed system). The size of the particles of '774 is within the instant range and the active agent is acetaminophen. The initial moisture content is provided either by water or an organic solvent such as ethanol and the K value for PVP is within the instant ranges. '774 does not specifically set forth initial moisture content within the instant range. However, '774 teaches that the initial

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moisture content is in an amount sufficient to moisten the ingredients but is insufficient to completely dissolve the binder.

9. **Claims 1-10, 12-27, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774) in view of Kumar (6,117,451; hereafter '451).**

10. '774 is relied upon for all that it teaches as stated previously. '774 does not teach the inclusion of dibasic calcium phosphate anhydrous in the product/process.

11. '451 is relied upon for teaching inclusion of dibasic calcium phosphate anhydrous in tablet formulations having PVP to improve flow and compression characteristics of the tableting powder.

12. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include dibasic calcium phosphate anhydrous in '774 with the motivation of providing improved flow and compression to the formulation of '774.

13. **Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774) in combination with Kumar (6,117,451; hereafter '451) and further in combination with Ansel et al (1999).**

14. '774 and '451 are relied upon for all that they teach as stated previously. Neither reference teaches tablets in capsules.

15. Ansel teaches insertion of tablets into capsules to produce a formulation with a desired amount of active.

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16. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine tablets into a capsule with the motivation of providing a single unit formulation having a particular desired dose.

17. **Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774) in view of Rudnic (Remington, 1995).**

18. '774 is relied upon for all that it teaches as stated previously. '774 does not teach inclusion of crospovidone in the formulation.

19. Rudnic is relied upon for teaching inclusion of crospovidone in tablet formulations to facilitate breakup of the formulation.

20. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include crospovidone in the formulation of '774 with the motivation of facilitating the disintegration of the formulation.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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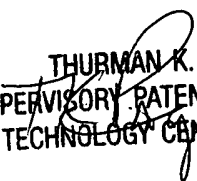
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308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw

September 25, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600